DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Zoll Medical Corporation
Tanmay B. Shukla
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824-4105

Re: K133239
Trade/Device Name: E Series Automated External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: December 12, 2014
Received: December 15, 2014

Dear Tanmay B. Shukla,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K133239

Device Name: **E Series**

Intended Use:

Defibrillator Function
The E Series products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

The E Series products must be prescribed for use by a physician or medical advisor of an emergency response team.
Do not use the unit's AED function on patients under 8 years of age.

Intended Use — Manual Operation
Use of the E Series products in the Manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In Manual mode, the E Series unit may also be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardias (VT) by using the R-wave of the patient's ECG as a timing reference. A qualified physician must decide when synchronized cardioversion is appropriate.

The Advisory function should be used to confirm ventricular fibrillation and wide complex ventricular tachycardia (greater than 150 beats per minute) in patients meeting the three conditions indicating lack of circulation (previously listed).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Intended Use — Semiautomatic Operation (AED)

The E Series AED unit is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.
They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation.

Intended Use — CPR Monitoring
The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

Intended Use — Pacemaker
This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

• **Resuscitation from standstill or bradycardia of any etiology**
Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

• **As a standby when standstill or bradycardia might be expected**
Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

• **Suppression of tachycardia**
Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Monitor – Intended Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO2), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), End Tidal CO2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

ECG monitoring is performed by connecting the patient to the unit via the 3 or 5 lead patient cable, MFE Pads, or through the paddles.

SpO2 monitoring is indicated for detecting arterial oxygen saturation of blood and pulse rate for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpCO monitoring is indicated for detecting carbon monoxide concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpMet monitoring is indicated for detecting oxidized hemoglobin concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO2 monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO2) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction or other cardiac arrhythmias.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A.

978-421-9655
978-421-0025 Main Fax

510(k) Summary:

Applicant's Name and Address:	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824
Application Correspondent:	Tanmay Shukla 978-421-9171
Date Summary Prepared:	April 22, 2014
Classification:	Class III
Device Name	ZOLL E Series
Product Code	Automated External Defibrillators (MKJ) Cardiopulmonary Resuscitation Aid (LIX) Low-Energy – Defibrillators (LDD) Cardiac Monitors – including Cardiotachometer and Rate Alarms (DRT) External Transcutaneous Cardiac Non-Invasive Pacemaker (DRO) Noninvasive Blood Pressure Measurement System (DXN) Blood Pressure Computer (DSK) Carbon Dioxide Gas Analyzer (CCK) Oximeter (DQA)
Predicate Devices	ZOLL E Series (K111594)

Description:

The ZOLL E Series® Defibrillator, reviewed and cleared by FDA under premarket notification K111594, is designed for all emergent care situations and provides multi-parameter monitoring of patients in critical care and transport. The ZOLL E Series combines defibrillation, CPR feedback, ECG monitoring, noninvasive transcutaneous pacing, pulse oximetry (SpO2), end tidal CO2 (EtCO2), 12-Lead ECG monitoring, non-invasive blood pressure measurement and data printing and recording in a single instrument.

The previously cleared Shock Conversion Estimator (SCE), initially reviewed and cleared by the agency under K072923, utilizes Shock Predictive (SPI) as a parameter in the shock advisory algorithm. Shock Predictive Index number is also called "Amplitude Spectral Area (AmSA) value" of the ECG Waveform, developed by the Weil Institute of Critical Care Medicine. In the previously cleared version of the E-Series, when the E Series device is configured to enable the Shock Conversion Estimator (SCE) function, the software compares the calculated Shock Predictive Index (AmSA) against a user-configurable threshold during shock advisory rhythm analysis. If the rhythm is shockable and the computed index is greater-than or equal-to the pre-configured threshold, the shock advisory algorithm will then issue a "Shock Advised" prompt to the user. If the Shock Predictive Index (AmSA) is less-than the threshold, the shock advisory algorithm will then issue a "Continue CPR" prompt to the user.

With the current application, we are proposing a software revision that will enable the E Series device to display the calculated Shock Predictive Index (AmSA) when used in manual mode with CPR defibrillation electrodes. After the trained rescuer has confirmed the ECG rhythm by manually analyzing the characteristics of the ECG waveform, the rescuer may utilize the displayed Shock Predictive Index (AmSA) value to perform the same function as the Rhythm Analysis Function Shock Conversion Estimator (SCE), reviewed and cleared by the agency under K072923.

Intended Use:

The E Series products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation. The E Series products must be prescribed for use by a physician or medical advisor of an emergency response team. Do not use the unit's AED function on patients under 8 years of age.

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The Advisory function should be used to confirm ventricular fibrillation and wide complex ventricular tachycardia (greater than 150 beats per minute) in patients meeting the three conditions indicating lack of circulation.

Intended Use — Semiautomatic Operation (AED)

The E Series AED unit is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation.

Intended Use — CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

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• **Resuscitation from standstill or bradycardia of any etiology**
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It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

• **As a standby when standstill or bradycardia might be expected**
Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

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Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Monitor – Intended Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO2), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), End Tidal CO2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

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SpMet monitoring is indicated for detecting oxidized hemoglobin concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO2 monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO2) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction or other cardiac arrhythmias.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.

Substantial Equivalence – Non-Clinical Evidence:
When enabled, E Series device can display the calculated Shock Predictive Index (AmSA) in the manual mode enabling the operator to perform the same function as the Rhythm Analysis Function Shock Conversion Estimator (K072923) except that the following steps, which would otherwise be performed by the machine, would now be performed manually by the operator:

- Determining whether the rhythm is shockable or non-shockable.
- If shockable, comparing the displayed Shock Predictive Index (AmSA) with the selected Shock Predictive Index (AmSA) threshold (decided by the Medical Director per local protocol) and making an appropriate treatment decision.

Safety, efficacy and substantial equivalence was shown through software verification and system level validation.

Substantial Equivalence – Clinical Evidence:
N/A - Clinical evidence was not necessary to show substantial equivalence

Comparison of Technological Characteristics

The ZOLL E Series utilizes the same features and functions as the indicated predicate device: ZOLL E Series (K111594). Through a software revision, the Shock Predictive Index (AmSA) that was calculated and utilized in the Rhythm Analysis Function Shock Conversion Estimator (K072923) can now be displayed on the E Series device screen when used in manual mode. The rescuer may utilize the Shock Predictive Index (AmSA) to perform the same function as the Rhythm Analysis Function Shock Conversion Estimator (K072923) in a manual mode.

Performance Testing:

Extensive performance testing in the form of the software verification and system level validation ensures that the ZOLL E Series performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. The use of the AmSA value in estimating the likelihood of defibrillation success is supported by the following literature that is cited in the submission:

1. Povoas H, Weil MH, Tang W, Bisera J, Klouche K, Barbatis A. Predicting the success of defibrillation by electrocardiographic analysis. Resuscitation 2002; 53:77-82.
2. Pernat AM, Weil MH, Tang W, Pernat A, Bisera J. Optimizing timing of ventricular defibrillation. Crit Care Med 2001; 29:2360-5.
3. Young C, Bisera J, Gehman S, Snyder D, Tang W, Weil MH. Amplitude spectrum area: measuring the probability of successful defibrillation as applied to human data. Crit Care Med 2004; 32:S356-8.
4. Ristagno G, Gullo A, Berlot G, Lucangelo U, Geheb E, Bisera J. Prediction of successful defibrillation in human victims of out-of-hospital cardiac arrest: a retrospective electrocardiographic analysis. Anaesth Intensive Care 2008; 36:46-50.

5. Li Y, Ristagno G, Bisera J, Tang W, Deng Q, Weil MH. Electrocardiogram waveforms for monitoring effectiveness of chest compression during cardiopulmonary resuscitation. Crit Care Med 2008; 36:211-5.

Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

The information provided in this 510(k) demonstrates that the ZOLL E Series' features and functions are substantially equivalent to those of the indicated commercially distributed devices with regard to performance, safety and effectiveness.